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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,697

09/27/2006

Gerard Marguerie

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EXAMINER

FINN, MEGHAN R

ART UNIT

PAPER NUMBER

1614

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,697	<b>Applicant(s)</b> MARGUERIE ET AL.	
	<b>Examiner</b> MEGHAN FINN	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/27/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's election without traverse of Compound CGP02-01 in the reply filed on November 17, 2008 is acknowledged.

Claims 8-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant elected the species with out traverse in the reply filed on November 17, 2008.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, applicant claims A represents an aromatic group of one or several cycles "possibly comprising" one or more heteroatoms or group B "a possibly substituted" pyridine group. This language is unclear and indefinite as one of skill in the art would not be able to determine if these limitations (the heteroatom or pyridine group) are required by the claims or not. In claim 2 applicant uses the language "more particularly of fluoride" in reference to what R3-R7 can be, and this is not clear because the language is not apparent whether this halogen is a required limitation or not. Also in claim 2, "preferably in the para position" is also unclear, for the same reasons. In

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claims 5 and 13 applicant claims "preferentially a fluoride" which is also unclear due to it not being apparent whether fluoride is a required limitation or not. Since one of skill in the art would not be able to determine if these compounds are required or not by the claims, due to the ambiguous language, claims 1-5 and 13-18 fail to particularly point and distinctly claim the subject matter which applicant regards as the invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, and 13-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the elected species and structurally similar compounds, does not reasonably provide enablement for the entire scope of the compounds encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant has claimed in claim 1, a very generic structure encompassing millions of compounds, which have very different core structures from the elected species. While applicant has shown how to make and use the elected species, they have provided no direction towards the multitude of compounds that have very different structure that one of skill in the art at the time of the invention would not expect the synthesis of use of the two compounds to be similar. Furthermore, applicant has only

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indicated a use for the elected species and has provided no information towards the use/effectiveness for other compounds that are structurally very different. Lastly, it is noted that in claims 16-18, applicant claims intended uses for the compounds, which carry no patentable weight, however it is noted that applicant has claimed the intended use of prevention various disorders, and the use for prevention of those diseases is not enabled for any of the compounds.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The amount of experimentation necessary to make and use some of the claimed compounds is large (1) and there is no direction provided and no working examples directed toward compounds other than the elected species (2,3). The nature of the invention is compounds that very significantly in structure and function (4) and the state of the prior art is such that while some compounds are known, the claims encompass millions of compounds, some of which are not known and applicant has not provided any information on them (5). The relative skill of those in the art is high (6), however the

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unpredictability of the synthesis of complex organic compounds such as those claims is also high (7). The breadth of the claims is large due to the large number of compounds encompassed by the claims (8).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cai et al. (US 2003/0105140 A1).

Applicant has claimed a variety of compounds encompassed by the formula (I) of claim 1. Cai et al. teaches many compounds that are encompassed by that formula (page 2, [0013], and page 6, [0151]), where A is a substituted aryl group, with a heteroatom, and R1 is hydrogen, R2 is also hydrogen and B is a substituted phenyl. These compounds read upon claims 1-5, and Cai et al. also teaches pharmaceutically acceptable salts (page 2, [0017]) as well as pharmaceutical compositions (page 2, [0025]) and thus anticipates claims 1-5, and 13-18.

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***Claim Rejections - 35 USC § 103***

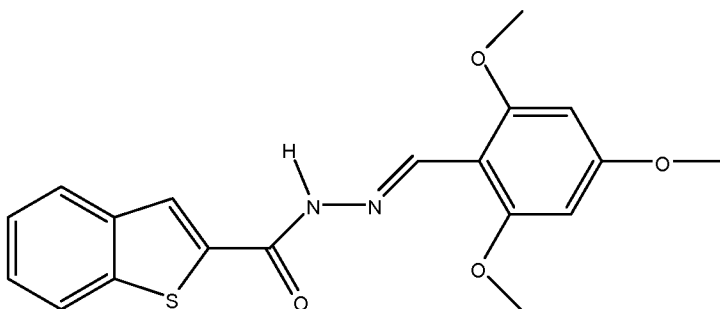
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai et al. (US 2003/0105140 A1).

Applicant has elected compound CGP02-01, which has the following structure:



While Cai et al. does not explicitly teach this specific compound as it does other compounds encompassed by the claims (as discussed in the 102 rejection), the elected species is clearly within the scope of the claims of Cai et al. They claim a generic formula I (page 3, [0033-0039]) where X is S, R<sub>2</sub>-R<sub>6</sub> are H, and R<sub>12</sub> is H, and Ar<sub>1</sub> is a substituted aryl group. Furthermore, in formula II, the specific aryl group of the elected species is R<sub>11</sub>, R<sub>9</sub> and R<sub>7</sub> being a alkoxy group and R<sub>20</sub>, R<sub>9</sub> being H (page 3, [0041-0044]). The core structure is the same, and it would have been obvious to one of ordinary skill in the art at the time of the invention that the elected species is disclosed by Cai et al. and thus claims 1-7 are unpatentable over Cai et al.

As discussed above, Cai et al. also claims a composition and pharmaceutically acceptable salts and thus claims 13-18 are also unpatentable over Cai et al.

### **Conclusion**



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No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

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